

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	R. K. Yang et al.	Examiner:	Chan, Sing P.
Application No.:	10/074,272	Group Art Unit:	1734
Confirmation No:	4926	Docket:	1199-4 RCE
Filed:	February 14, 2002	Dated:	May 9, 2006
For:	THIN FILM WITH NON- SELF-AGGREGATING UNIFORM HETERO- GENEITY AND DRUG DELIVERY SYSTEMS MADE THEREFROM		

Commissioner for Patents
P.O. Box 1450,
Alexandria, VA 22313

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On: May 9, 2006

Signature: K.J. Goodhand / *K.J. Goodhand*

DECLARATION BY RHYTA S. ROUNDS, Ph.D. UNDER 37 C.F.R. §1.132

Sir:

I, Rhyta S. Rounds Ph.D., do hereby make the following declaration:

I. Technical Background

1. Attached as Exhibit A is a copy of my curriculum vitae. As noted therein, I have worked in the field of material science, particularly experimental rheology, for 30 years.

2. My work experience includes 11 years as the Research Director of Fluid Dynamics, Inc., 2 years of employment with Becton Dickinson Vacutainer Systems, 9 years of

employment with Colgate-Palmolive Company and 1 year of employment with CPC Americas. During these periods of employment, I worked extensively with the rheology of various fluid systems, including the processing of complex fluids. I have worked on structured fluid systems for application to the pharmaceutical, food, cosmetic/toiletries and coatings and adhesives industries.

3. During my career, I was an inventor on numerous patents directed to complex fluid systems. I have direct experience with fluid systems which produce mottle, as well as an understanding of the uniform distribution of active/unit volume of the present invention.

4. I have been hired as a consultant by MonoSolRx, LLC (the assignee of the above-identified application) to provide an expert analysis on an issue related to the prosecution of U.S. Application No. 10/074,272 (hereinafter the "Invention" or "Present Application"). While I am being paid for my services, I am not an employee of MonoSolRx, LLC nor do I have any financial interest in MonoSolRx, LLC.

5. I have reviewed a copy of U.S. Patent No. 5,881,476 to Strobush et al. (hereinafter "Strobush") and the January 20, 2006 Office Action issued with respect to the subject application. I also have reviewed the Present Application. I have been requested to provide my opinion as to the technical distinctions between mottle and compositional uniformity as they are each defined in Strobush and the Present Application, respectively. I have also been requested to provide an analysis as to applicability of the Strobush teachings to water-based processes to make water-soluble film with a uniform distribution of active/unit volume.

6. In the Office Acton, the Examiner equates mottle with compositional uniformity. "Mottle" as defined in Strobush is a technical problem different from "Compositional Uniformity" as defined in the Present Application.

II. Strobush and the Present Application Relate to Entirely Different Technologies

7. To begin with, Strobush relates to technology which is in an entirely different field than the Present Application. Strobush is directed to non-ingestible coated substrates used

in the manufacture of imaging articles. The coatings applied to the substrate are non-aqueous, particularly alcohol/ketone-based, colloidal emulsions. Such systems are highly volatile and typically have low viscosities.

8. In contrast, the Present Application is directed to ingestible films for the oral delivery of actives, particularly pharmaceutical actives. The films of the Present Application are aqueous systems, which include dispersions of relatively large active particles in a viscous water-based matrix. The Present Application forms a highly viscoelastic matrix.

III. Definition of Mottle

9. Strobush teaches a process and apparatus for producing thin, mottle-free photothermographic, thermographic and photographic coatings on a substrate. A complex drying apparatus is described in detail with a plurality of zones expressly designed to control and eliminate mottling. A definition of what is meant by mottle is provided in column 1, lines 59-67 and column 2, lines 1-5:

Mottle is an irregular pattern or non-uniform density defect that appears blotchy when viewed. This blotchiness can be gross or subtle. The pattern may even take on an orientation in one direction. The scale can be quite small or quite large and may be on the order of centimeters. Blotches may appear to be different colors or shades of color. In black-and-white imaging materials, blotches are generally shades of gray and may not be apparent in unprocessed articles but become apparent upon development.

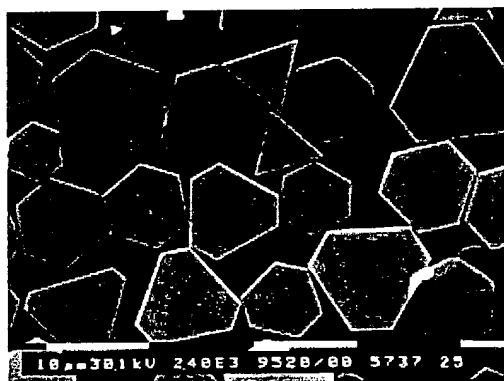
10. In short, mottle, in the context of Strobush, relates to visually observable surface defects on a substrate coating. Mottle is further described by Strobush in column 2, lines 6-19, as being “an undesirable defect because it detracts from the appearance of the finished product.”

11. Mottle is repeatedly stated as the problem being addressed in Strobush, and in fact, it is the sole problem addressed by Strobush. For example, see SUMMARY OF THE INVENTION, column 6, lines 24-29, where it is expressly stated that drying coated substrates can be accomplished “...without introducing significant mottle...” The disclosure is replete with

express statements regarding the invention's purpose of "minimizing the formation of mottle". Exhibit B, attached hereto, sets forth 28 passages in Strobush where the problem to be overcome is expressly stated as reducing mottle.

12. Mottle is a serious problem for Strobush because Strobush's emulsion system is largely composed of highly volatile organic solvents, such as 2-butanone (methyl ethyl ketone or MEK), in which many of the emulsion ingredients are dissolved. *See* Strobush, Col. 2, lines 16-19.

13. The coatings used in Strobush are extremely thin and could not function independent of a permanent substrate. Film coatings in the liquid phase are cited in Strobush as being sub-millimeter (<10 mil), which is extremely thin (on the order of microns). *See* Strobush Examples 1 and 2 (wet emulsion layers are 81.3 microns and 91.4 microns, respectively). Strobush's thin coatings are not capable of being self-supporting films. They are designed to be part of a laminate or multi-layer structure, with the substrate being integral with and inseparable from the coating, such as in a photograph. The emulsion layer, as defined in Strobush (Column 7), contains a photosensitive silver halide or reducible silver source. Silver halide is a photoactive microcrystalline solid, as shown in the photomicrograph below:



**Electron micrograph of tabular
grain emulsion**

(from Kodak)

14. Silver particles useful in such emulsion coatings are microscopic and are understood to those skilled in the art to be one (1) micron or less. *See* R.J. Stokes et al.,

Fundamentals of Interfacial Engineering, 120 (1997). The silver behenate core/shell particles actually used in Strobush have an average grain size of 0.04-0.05 μm . See U.S. Patent No. 5,382,504, Col. 23-24 (cited in Strobush at Col. 18, lines 40-41). The silver particles must be aligned properly on the substrate surface in order to prevent imperfections, i.e., mottle, in the appearance of the photo- or thermo-developed image. These small particles are highly energetic surfaces, with high surface areas. Consequently, as a colloid, interfacial forces and physical chemistry govern their behavior. With appropriate particle surface treatments, steric stabilization and Brownian motion maintain sol physical stability.

15. Strobush addresses the problem of mottle in its coatings using a complex drying apparatus, which includes a sequence of zones. In Strobush, the multi-zoned and sub-zoned apparatus is critical to minimizing or reducing defects in coating appearance, which would blur or otherwise detract from the image produced by the coating. Strobush's apparatus and process controls the colloid and surface properties of its solvent based emulsion and other layers by controlling the heat transfer rate and temperature difference between the temperature of the drying gas and the temperature of the coated substrate, i.e., emulsion layer laminated to the underlying photographic paper or other substrate.

16. To obtain a photo- or thermo-graphic image which is not blurred or blotched, Strobush dries his very thin coatings in an elaborate sequence of zones in order to control the evaporation rate of volatile, non-aqueous solvent and prevent disruption or the preferential alignment of the sub-micron sized silver particles. By doing so, Strobush reduces or minimizes mottle.

17. In summary, the problem of mottle in Strobush involves a blurred or blotchy coating, which is undesirable in a photographic coating.

IV. Definition of Compositional Uniformity

18. Compositional uniformity as expressed in the Present Application means that during processing, the composition must maintain uniformity in content of all components such that the product formed contains the same amount of active throughout (within acceptable

regulatory variances), as well as a uniform product thickness (“Compositional Uniformity”). *See* U.S. Application No. 10/074,272, ¶ [0010]. This is critical for drug-containing films in order to provide safe and effective consumer products and thereby satisfy FDA-approval requirements. Stringent government controls in the production of pharmaceutical products are mandated by federal law and without uniform active content, such products cannot be legally used or sold. For example, a 250µm thick x 1” x ½” piece of dry film, cut from one region of a manufactured roll, must contain the same components in substantially the same relative amounts as an equally-sized piece of film cut from another region of the manufactured roll.

19. To achieve this, a flowable wet film-forming composition containing ingestible active dispersed or dissolved in a non-toxic liquid, e.g., water, must first be formed which can be laid down onto a drying surface as a uniform composition. Mixing of the components to form the composition must be done thoroughly and in a manner to ensure uniformity, particularly of the active, and to prevent excess air from being pulled into the mixture. Excess air produces random voids within the film during drying, which can destroy Compositional Uniformity.

20. Once the uniform wet film composition is laid onto a drying surface, the water component must be evaporated and the film must be dried through a process that prevents the dispersed phase containing the active from migrating or aggregating. This problem is solved by quickly maintaining and further enhancing the viscoelastic state such that uniformity of the components in the film is “locked in.” This is accomplished by bottom drying, without disturbing the physical thickness of the film by excessive top air flow. The combination of steps of the Present Application prevent migration or aggregation of the dispersed phase, prevent surface skinning and re-rupture as water evaporates, and minimize trapped air voids, which would otherwise be present if surface skinning occurred. The result is a self-supporting film product that can be divided into dosage units and safely ingested due to its Compositional Uniformity.

V. Mottle is a Different Technical Problem than Compositional Uniformity

21. In the Office Action, the Examiner equates the problem of mottle with the Present Application’s problem of Compositional Uniformity. *See* Office Action, at page 6. Mottle,

however, is a different technical problem than achieving Compositional Uniformity throughout a film, particularly as the films of the Present Application are distinctly different from the coatings taught by Strobush and require different processing considerations.

22. As seen above, solving the problem of mottle in an emulsion system based on highly volatile solvents, as taught in Strobush, does not address in any way the problem of Compositional Uniformity in a drug delivery system based on aqueous dispersions of particles.

23. The problem addressed in the Present Application is finding a process for obtaining bulk Compositional Uniformity throughout a self-supporting oral dosage film strip. The Present Application seeks to make relatively thick, self-supporting films, which do not require a backing or laminate structure to perform their function. Wet film thickness is on the order of 500-1,500 μm (micron). See U.S. Application no. 10/074,272, at ¶ [0091]. The product produced from the inventive process is an oral dosage film strip for delivery of an active, such as a flavor or drug, to a consumer.

24. Contrary to the very thin colloidal photographic coatings made by Strobush, when particles of actives are present in the inventive films, they are significantly larger, e.g., drug particles are typically 50 microns or greater, more specifically about 50 to 250 microns. Further, these particles are typically irregular in size and shape and are present in a distribution of particle sizes, unlike silver halide, for example. The problem of creating a self-supporting film product that includes such large particles and that has Compositional Uniformity is entirely different from the problem of producing a mottle-free photographic emulsion coating.

25. The relatively large suspended particles, such as drug particles, in the films of the Present Application, behave very differently than the small colloidal particles of Strobush's coatings. Large particle dispersions, such as in the Present Application, typically migrate, fall out of solution and/or aggregate. Colloidal emulsions, such as in Strobush, do not experience such problems. For example, milk is a colloidal emulsion. Milk retains its suspension without experiencing separation problems. This is typical of colloidal emulsions. Large particle dispersions present completely different technical challenges and problems than small colloidal

systems, such as shown in Strobush. Brownian motion, long range attractive and repulsive forces, for example, are significant factors in colloid systems; external forces, such as gravity, are far more important in large particle dispersed systems. Obtaining a dried, relatively thick film with the proper amount of active distributed throughout is unrelated to the surface appearance, and in fact surface imperfections in the inventive films are expected. Large particles adjacent the film surface may create a rough appearance or sandpaper-like effect. Such surface imperfections are entirely acceptable and in fact expected in the Invention.

26. In fact, Strobush itself recognizes that mottle is a different problem from other surface defects in aqueous systems. In particular, mottle, according to Strobush, is a different problem than surface bubbles and blistering formed when aqueous, latex paint dries. At Column 4, lines 6-9, Strobush states that the “formation of mottle occurs due to a different mechanism than blisters and requires a different method for control and elimination.” Thus, even among other surface defects formed by drying coatings, mottle is seen by Strobush as a different problem.

VI. The Strobush Process has Numerous Contrary Teachings and Characteristics to the Invention and Water-Based Processes

27. A careful reading of Strobush indicates its contrary teachings from the Present Application. Tabulated below are examples of some of the process characteristics that play a role in each of the Present Application and in Strobush. As the table indicates, the differences are cogent reminders of different considerations and goals of the two processes.

Inventive Process Characteristics	Strobush Process Characteristics
Edible film	Photographic coating
Water	MEK (highly volatile toxic organic solvents)
Viscoelastic matrix	Low viscosity (rheology not mentioned)
Active (e.g., temperature-, oxidative- and/or hydrolytically-sensitive)	No ingestible actives
Relatively large particles (macro-suspension)	Nanoparticles (colloidal dispersion)
Self supporting doses	Permanent thin coating on a substrate
Rapid heating to create large temperature differential	Very small temperature differential in a plurality of heating zones
Benard cells	No Benard cells
De-aeration	De-aeration not possible
Compositional uniformity (mass of active/unit volume)	Mottle free (perfect surface)
Surface imperfections generated (mottle is acceptable)	No surface imperfections

28. In view of these stark differences, one skilled in the art would not consider Strobush relevant or applicable to water-based, edible systems, and would not be inclined to consult Strobush to solve drying problems associated with water-based edible films.

29. One of ordinary skill in the art with respect to processes for making edible active-containing products, would not arrive at the Present Application from the teachings of Strobush. In fact, use of the Strobush process with the compositions of Zerbe would not be expected to produce the products of the Invention.

VII. Compositional Uniformity in Drug Products and the Process of Making Uniform Drug Products is Governed by FDA Requirements

30. Compositional Uniformity is vital for oral film delivery strips to provide safe and effective consumer products. Without Compositional Uniformity, individual film products containing drug cannot achieve FDA approval for consumer use and essentially have no value. The surface appearance of such film products is of no consequence to their consumer safety and efficacy and the FDA approval process, and thus, mottle is irrelevant to solving this problem.


VIII. Conclusion

31. The process of Strobush involves producing extremely thin photographic coatings by incrementally ramping up the temperature to avoid disalignment of silver particles in a solvent-based emulsion, which otherwise results in a defective image, i.e., mottle. The end-product is a photoactive coating on a substrate used to produce images. In contrast, the inventive process is directed to achieving self-supporting oral film strips for delivery of actives by controlling and "locking in" the physical properties of the composition during the drying process, such that uniformity in the composition is maintained. The final product is an active-containing strip for safe and efficacious delivery to a consumer. Strobush's process of producing a photographic coated substrate is not technically germane to the production of an oral dosage film strip having Compositional Uniformity.

32. Therefore, mottle as taught by Strobush is an entirely different problem from Compositional Uniformity throughout a film. Moreover, the two different technical problems are addressed using two different processes to achieve entirely different products.

33. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Dated this 9th day of May, 2006



Rhyta S. Rounds Ph.D.

EXHIBIT A

**Rhyta Sabina Rounds
68 Sand Hill Road
Flemington, New Jersey 08822
(908) 303-4920**

SUMMARY OF QUALIFICATIONS:

More than thirty years of progressive industrial experience in material science. Emphasis has been in experimental rheology, in support of product/process development and manufacturing. Hold advanced degrees in Chemical Engineering.

PROFESSIONAL EXPERIENCE

Fluid Dynamics, Inc
45 River Road
Flemington, NJ 08822

Research Director 1995-present

Organized independent commercial rheology laboratory focused on complex fluid technology. Primary objective of this laboratory is two-fold : worldwide rheology testing and basic research in structured fluid systems for application to the pharmaceutical, foods, cosmetic/toiletries, coatings and adhesives industries as well as the design/manufacture of rheology testing instrumentation.

Becton Dickinson Vacutainer Systems 1993-1995
1 Becton Drive
Franklin Lakes, New Jersey

Research Fellow 1994-1995

Responsible for development of next generation serum/plasma separation medical devices having improved compatibility with diverse diagnostic immunoassays.

Senior Manager 1993-1994

Directed R&D Worldwide Technical Support in specimen separation blood collection medical devices. Manager of Materials Technology and Analytical Sciences groups. Responsible for maintenance and revitalization of product line accounting for 80% of division profitability.

Managed staff of eight with operating/project budget in excess of \$1.5MM.

Worldwide team leader for collaborative research programs for improved immunoassay diagnostics.

- Developed interactive R&D/Marketing/Sales/Customer Service team for rapid response to customer complaints in serum/plasma blood collection tubes.
- Coordinated joint supplier/R&D teams for increased quality of incoming raw materials and revised

specifications.

- Developed strategic alliances facilitating the development of next generation products.
- Identified manufacturing/raw material cost reductions in excess of \$1.75MM/yr.
- Implemented new production quality control measures increasing QC reliability and efficiency.
- Identified new gel chemistries for plasma/serum separation providing performance/cost advantage.
- Responsible for development of Gel Technology Center of Excellence.

Colgate-Palmolive Company
Technology Center
Piscataway, New Jersey

1984-1993

Senior Technical Associate

1991-1993

Worldwide Fabric Care Process Team Leader in Manufacturing Engineering Technology group. Responsible for process development/implementation for new liquid detergent products and optimization of existing production lines.

Managed staff of three with project activities in North America and the Far East with primary emphasis in Mexico, Malaysia and Australia.

- Developed core competency in rheology and the processing of complex fluids and surfactant systems.
- Identified process methods for liquid detergents resulting in cost savings of \$32M/yr and capital cost avoidance in excess of \$75M per production line.
- Identified accurate scale-up procedures for high volume-fraction liquid detergent dispersions from 1 liter to 20 metric ton plant scale operations.
- Revised raw material specifications worldwide for increased quality control and improved product performance.

Research Associate
Senior Research Engineer
Research Engineer

1988-1990

1986-1988

1984-1986

Managed rheology research group of three with department budget of \$340M.

- Established new R&D department with mission to develop core competency in stable complex fluids with strong skill base in rheology, material science and surfactant/physical chemistry.
- Developed state-of-the-art rheology lab supplemented with electrical property measurements and extensive data acquisition expertise.
- Developed next generation gel liquid dishwasher detergent with improved product stability and performance with market introduction FY89. Product evaluated by Consumer Reports to be the Best New Liquid Detergent in 1990.
- Coordinated external/internal research programs for product quality improvements in Oral Care, Fabric Care, Household Surface Care and Advanced Research groups.
- Identified alternative applications for detergent systems in energy storage devices resulting in licensing proposals for the new technology.

CPC Americas

1977-1978

Best Foods Division
Commerce Street
Union, New Jersey

Process Development Engineer

- Conducted pilot plant research leading to full-scale production.
- Start-up team member for vegetable oil hydrogenation processes.
- Evaluated catalysts for hydrogenation.
- Modeled sterilization processes for process control.

EDUCATION

Stevens Institute of Technology

Hoboken, New Jersey
Department of Chemical Engineering

Post-Doctoral Research Fellow

Research Topic: Enhanced Membrane Separation Processes Coupled with Rapid-Pressure Swing Adsorption
1983-1984

Ph.D., Chemical Engineering

Thesis: Dielectrically Enhanced Permeability of Glassy Polymer Films
Graduation: 1982

Masters of Engineering, Chemical Engineering

Thesis: Anisotropic Thermal Conductivity of Oriented PET Films
Graduation: 1980

Completed Undergraduate Curriculum in Chemical Engineering
1975-1977

Rutgers University

Newark Campus
Newark, New Jersey

Bachelor of Arts, Geography

Graduation: 1973

Patents

US Patent, 6,149,821: Balanced Water Purification System.

US Patent 6,120,698: Balanced Water Purification System.

US Patent 5,807,970: Blood compatible, shear sensitive formulations.

US Patent 5,663,285: Blood compatible, shear sensitive formulations.

US Patent 5,427,707: Thixotropic aqueous compositions containing adipic or azelaic acid stabilizer.

US Patent 5,525,241: Linear viscoelastic aqueous liquid automatic dishwasher detergent composition.

US Patent 5,245,512: Nonisotropic solution polarizable material and electrical components produced therefrom.

US Patent 5,232,621: Linear viscoelastic gel compositions.

US Patent 5,064,553: Linear-viscoelastic liquid automatic dishwasher detergent composition.

US Patent 5,053,158: Linear-viscoelastic liquid automatic dishwasher detergent composition.

US Patent 5,038,249: Nonisotropic solution polarizable material and electrical components produced therefrom.

US Patent 4,974,118: Nonisotropic solution polarizable material and electrical components produced therefrom.

US Patent 5,206,797: Nonisotropic solutions polarizable material and electrical components produced therefrom.

US Patent 4,878,150: Polarizable material having a liquid crystal microstructure and electrical components produced therefrom.

Presentations and Publications

2nd Edition in preparation. Liquid Detergents, Surfactant Science Series, Volume 67. Ed, K-Y Lai, Chapter 4, "Rheology of Liquid Detergent Systems", Marcel Dekker, 1997.

2nd Edition in preparation. Liquid Detergents, Surfactant Science Series, Volume 67. Ed, K-Y Lai, Chapter 14, "Processing of Liquid Detergents: A Manufacturing Overview", Marcel Dekker, 1997.

Rheology of reactive polymer systems. R. S. Rounds, ACS National Meeting, Application Rheology of Dispersed Systems, Boston, August 18, 2002.

ACS National Meetings, R S Rounds, Presiding: Application Rheology of Dispersed Systems, Boston, August 18, 2002.

Evaluation of the Rheological Properties of Sulfonic Acids and Sodium Sulfonates, Berna, J.L., Bengoechea, C., Moreno, A., Rounds, R.S. *Journal of Surfactants and Detergents*, 3,3, July 2000).

Sulphonic acids and sodium sulfonates. Rheological properties and phase behaviour. C. Bengoechea, A. Moreno, J. L. Berna, Petresa, Spain R.S. Rounds, Fluid Dynamics, USA. M. Caffrey, Ohio State University, USA, Personal Care Ingredients Asia, November, 1999.

Rheological Characterization of an Aluminum Nitride Nanoparticle Suspension in Poly(amic Acid)-NMP System, Mater. Res. Soc. Symp Proc. 501, Feb. 1998; with X. Chen and R. S. Rounds.

Powder Coating Institute Meeting, 1996, Cincinnati. Test Methods Development Sub-Committee, Invited Speaker. *Rheological Measurement of Curing Powder Coatings*.

Liquid Detergents, Surfactant Science Series, Volume 67. Ed, K-Y Lai, Chapter 4, "Rheology of Liquid Detergent Systems", Marcel Dekker, 1997.

Liquid Detergents, Surfactant Science Series, Volume 67. Ed, K-Y Lai, Chapter 14 Processing of Liquid Detergents: A Manufacturing Overview", Marcel Dekker, 1997.

HBA "96 Educational Conference, New York. Invited Speaker. *Model Systems for Testing Product Concepts: Setting Effective Guidelines for Product Development*.

Society of Cosmetics Chemists, 1995, New York. Key Note Speaker: *Product Development & The Product Delivery Vehicle*.

Bath Gels: Rheology and Consumer Perceptions. Cosmetics & Toiletries. April, 1995.

ACS National Meeting, 1993, Chicago. Session Chairperson: Polymers in Aqueous Media.

ACS National Meeting, 1993, Chicago. Short Course Lecturer: Polymeric Hydrophilic Gels.

Shear Induced Phase Transitions of Anionic Surfactant Pairs, ACS National Meeting, 1993, Chicago. Symposium: Rheology of Surfactant Solutions. Invited Speaker.

Shear Effects in Surfactant Solutions, ACS Symposium Series 578, eds. C Herb, R Prud'homme, ACS, 1994.

Hydration Kinetics of Water Soluble Polymers, Society of Rheology Meeting, 1990, Santa Fe.

Physical Stability of Concentrated Dispersions, AIChE Annual Meeting, 1992, Miami.

A New Supercapacitor as a Replacement of Rechargeable Batteries, Third International Rechargeable Battery Seminar, 1990, Florida.

Surfactants in Electric Double Layer Capacitors: Use as Load Leveling Devices in Electric Vehicles, Ford Motor Company, Michigan, 1989.

Rheology of Aqueous Clay Dispersions, Princeton University, Chemical Engineering Seminar Series, 1988.

Enhanced Permeability of Polymer Films, ANTEC, 1983.

Dielectrically Enhanced Permeability of Polymer Films, Plastics Institute of America, Stevens Institute of Technology, 1981.

Anisotropic Thermal Conductivity of Oriented PET Films, ANTEC, 1978, New Orleans.

EXHIBIT B

Column 2, lines 6-19	Mottle is “an undesirable defect because it detracts from the appearance of the finished product.”
Column 6, line 67-column 7, line 1	“...minimizing the formation of mottle as the coating solvent is evaporated.”
Column 9, lines 13-14	“...minimizing the creation of drying defects, such as mottle.”
Column 10, lines 5-6	“...mottle on the first and second coating edges is minimized.”
Column 12, lines 27-28	“dried without introducing significant mottle defects...”
Column 12, lines 40-41	“The heat transfer rate is the coating 12 is the key to preventing or minimizing mottle formation.”
Column 13, lines 30-31	“...without causing mottle...”
Column 13, line 38	“...to prevent mottle...”
Table I	“Maximum heat transfer rate without mottle formation -hΔT”
Column 13, line 66	“...mottle is not caused.”

Column 14, lines 11-12	“...without causing mottle.”
Column 14, line 24	“...while still avoiding mottle.”
Column 14, lines 29-30	“...without formation of mottle.”
Column 15, lines 29-30	“...formation of mottle is minimized or prevented.”
Column 15, line 47	“...to minimize mottle formation...”
Column 19, line 49	“...dried to be mottle proof...”
Column 19, lines 58-60 and 64-66	“...severity of mottle was determined...amount of mottle was subjectively determined...films were visually inspected for mottle...mottle was rated as high, medium or low.”
Column 20, line 3	“...level of mottle increased...”
Table 4	“Mottle Rating”
Column 20, line 21	“Drying more harshly increased the severity of the mottle.”
Column 20, lines 37-41	“In order to determine the effect on mottle...”
Table 5	“Mottle Rating”

Column 20, lines 63 & 67

“...the severity of mottle increased.”

Table 6

“Mottle Rating”

Column 21, line 22

“...the severity of mottle increased.”

Table 7

“Mottle Rating”

Column 21, line 42

“...the severity of mottle increased.”

Table 9

“Mottle Rating”

All claims are directed to a method or apparatus for evaporating a coating solvent from a coating on a surface of a substrate and “reducing mottle” as the solvent evaporates.